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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,637	08/02/2000	Jean Gosselin	2097/49123	8660

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	5

DATE MAILED: 11/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/631,637	Applicant(s) GOSSELIN ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a method of treating an infection with bpV compound, classified in class 424, subclass 9.2.

II. Claims 17-19 , drawn to a method of treating an infection with a combination of bpV and an antiviral agent, classified in class 514, subclass 50.

III. Claims 20 and 21, drawn to a method of treating an infection with a combination of bpV and an immunomodulator compound, classified in class 424, subclass 85.4.

IV. Claims 22-27, 29-35, drawn to a method for the enhancement of antimicrobial efficacy of antimicrobial agents with bpV, classified in class 435, subclass 32.

V. Claim 28, drawn to drawn to a method for the enhancement of antimicrobial efficacy of antimicrobial agents with bpV and an additional compound, classified in class 424, subclass 85.1.

VI . Claims 36-51, drawn to a composition with bpV, classified in class 424, subclass 646.

VII. Claims 53 and 54, drawn to a composition of bpV and an antiviral compound, classified in class 514, subclass 45.

VIII. Claims 55 and 56, drawn to a composition of bpV and an immunomodulator, classified in class 530, subclass 351.

Groups VI-VIII are compositions and are distinct from groups I-V which are drawn to methods. Groups VI-VIII are compositions and each is distinct from the other because they contain different materials. Group VI comprises bpV and pharmaceutical carriers. Group VII

comprises bpV and an antiviral compound in conjunction with a pharmaceutical carrier. Group VIII comprises bpV and an immunomodulator in conjunction with a pharmaceutical carrier. Though there may be overlap for groups VI-VII, the search for one group will not be coextensive with that of the other group.

Groups I-V are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Group I is drawn to a method of treating an infection with bpV. Group II is drawn to a method of treating an infection with a combination of bpV and an antiviral agent. Group III is drawn to a method of treating an infection with a combination of bpV and an immunomodulator. Group IV is drawn to a method of enhanhing the antimicrobial activity of a compound with bpV. Group V is drawn to a method of increasing the antimicrobial activity utlizting a compnination of compounds. The method of Group I-V use different material compositions from the other methods, in addition, the methods treat different infections thereby setting the groups apart from each other.

Additionally, Groups I and VI contains claims directed to the following patentably distinct invention, applicant is required to pick a single disclosed invention for Group I or VI:

i. DNA virus, classified in class 424, subclass 229.1.

i. RNA virus other than retrovirus, classified in class 242, subclass 216.1.

iii. Retrovirus, classified in class 424, subclass 187.1.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the

reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Additionally, Groups I, IV and VI contain claims directed to the following patentably distinct species of the claimed invention:

1) Human
2) Ovine
3) Bovine
4) Equine
5) Caprine
6) Porcine
7) Feline
8) Canine

The species are phenotypically and genotypically distinct. The examination of species 1-8 in the method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Additionally, Groups I, VI and VI contain claims directed to the following patentably distinct species of the claimed invention:

1) Intravenously
2) Subcutaneously
3) Intradermally
4) Transdermally
5) Intraperitoneally
6) Orally
7) Topically

The examination of species 1-7 in the method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Additionally, Groups I, VI and VI contain claims directed to the following patentably distinct species of the claimed invention:

1) Patch
2) Implant
3) Inhalation
4) Aerosol spray
5) Powder
6) Liposomal composition
7) Tablet

The examination of species 1-7 in the method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Additionally, Groups II and VII contain claims directed to the following patentably distinct species of the claimed invention:

1) Nucleoside analogs
    a. AZT
    b. 3TC
2) Protease inhibitor
3) Neuramidase inhibitor
4) Interferon alpha
5) Non-nucleoside inhibitor

The species differ in their physical, immunological properties and activity in the viral life cycle and are distinct and unobvious in view of each other and are therefore patentably distinct.

Additionally, Group V contains claims directed to the following patentably distinct species of the claimed invention:

1) Nucleoside analogs
    a. AZT

b. 3TC
2) Protease inhibitor
3) Neuramidase inhibitor
4) Interferon alpha
5) Non-nucleoside inhibitor
6) Non-nucleoside reverse transcriptase inhibitor (NNRTI)
7) Chemokines
8) Chemokine antagonist

The species differ in their physical, immunological properties and activity in the viral life cycle and are distinct and unobvious in view of each other and are therefore patentably distinct.

Additionally, Groups III and VIIII contain claims directed to the following patentably distinct species of the claimed invention:

1) Leukotrienes
2) Chemokines
3) Cytokines
4) Growth factors
5) Interferons

The species differ in their physical, immunological properties and are distinct and unobvious in view of each other and are therefore patentably distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 11/19/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600